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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,415	02/11/2004	Ramkumar Subramanian	ALZ5116USANP	4311

27777 7590 09/06/2007

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	
MAIL DATE	**DELIVERY MODE**
09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,415	SUBRAMANIAN ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/10/2004 and 08/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 06/10/2004 and 08/30/2004 is acknowledged.

Restriction /election

Applicant's election of Group I without traverse in response to Office action dated 06/19/2007 is acknowledged. Claims **5-27 and 30-38** stand cancelled. Claims pending in this Application are **1-4 and 28-29** and will be prosecuted on the merits.

DOUBLE PATENTING

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4 and 28-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/754351. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the applications comprise overlapping subject matter. Copending application claims a dosage form for delivery of a drug to a patient, the dosage form comprising:(a) an inner wall defining an internal compartment; (b) a core within the internal compartment comprising a drug layer, the drug layer having a drug therein; (c) an outer wall around at least a portion of the inner wall and the core, the outer wall and the inner wall having at least one exit there through and communicating with the core; (d) the dosage form having a delay period wherein the drug is not delivered through the at least one exit for a period of about 4 hours after administration and a delivery period wherein the drug is delivered through the at least one exit in a controlled fashion for a period of about 16 hours after the delay period. Similarly, the claims of instant application are drawn to dosage form comprising (a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable;

(b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semipermeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice;

(d) a drug layer located within the compartment between the delay layer and the expandable layer; and

(e) an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.

The difference between the copending application and the instant application is that the copending application recites the release rates. It would have been obvious to the one of ordinary skilled in the art to optimize the release rate by manipulating the amounts of active dose and the excipients.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/62496 ('496) in view of Jao et al. (US patent no. 5252338) and further in view of Eckenhoff et al. (US patent No. 4717566) and Theeuwes (US Patent no. 4,111,202).

('496) discloses methods and devices for maintaining a desired therapeutic drug effect over a prolonged therapy period. In particular, oral dosage forms that release drug within the gastrointestinal tract at an ascending release rate over an extended time period (abstract). ('496) discloses bilayer and trilayer oral osmotic dosage forms. The bilayer has first component layer comprising a selected drug and excipients for forming a deliverable drug composition when hydrated and a second push layer, comprising a fluid expansion osmopolymer and excipients, contained within the compartment formed by a semipermeable membrane and having an exit means to release the drug. The two layers are compressed together to provide a longitudinally compressed tablet core having a shape of a "capsule shaped configuration. (see page 7, lines 5-17). The trilayer oral osmotic dosage forms include a novel trilayer tablet core surrounded by a semipermeable memberane and having suitable exit means for releasing the drug formulation through the semipermeable membrane. The tablet has a first drug containing layer, a second drug containing layer and a third push layer. During operation, the drug is successively released from the first drug containing layer and then from the second drug containing layer. The drug concentration gradient facilitates the achievement of an ascending drug release rate for an extended time period. Consequently the excipients in the drug-containing layer may be flexibly varied and adjusted for manufacturing convenience and the dosage forms thus exhibit drug release having the desired sustained and ascending rate over an extended time period. (see page 8, lines 1-10). Various drugs that are used are depicted on page 8, lines 25-30. Example 5 depicts trilayer oral osmotic dosage forms having a drug concentration

variance wherein the viscosity of first component was lower than the second which in turn was lower than the third. The example shows an ascending release rate for an extended time period. Sequential compression of various component layers is shown on page 35, lines 15-20).

The reference does not teach delay layer as the first component layer, located adjacent to the exit orifice.

However, Jao et al. teach a dosage form comprising means for delaying delivery of drug from the dosage form following the administration of the drug (see drawing of figure 3-5). On column 4, Jao et al. show how the polymeric delay layer along with the drug in it helps in delaying the delivery of the drug. The polymeric means possesses a slow rate of hydration dependent on the molecular weight and viscosity. The dosage form can take wide variety of shapes such as oral and buccal etc. (see column 5, lines 34-35).

Jao et al. do not teach the convex geometry as claimed in an instant application, however, Eckenhoff et al. teach a dosage form for delivering a beneficial agent with a convex geometry. The dosage form comprises a wall that surrounds and defines an internal space, a composition comprising a beneficial agent, means for aiding beneficial agent for delivering the composition. (see abstract and drawing on the abstract page and fig 30.).

Theeuwes teaches an osmotic system for the delivery of active agent over time. The system comprises a wall surrounding an agent compartment and an osmagent compartment separated by a film and has a passageway through the wall for delivering

the agent from its compartment. (see abstract and the picture depicting convex configuration formed at the time of release.).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate a delay layer in place of first drug component in the dosage form of ('496) based on the teachings of Jao et al. and have an interface boundry between the delay layer and the drug layer having a convex configuration as taught by Eckenhoff and Theeuwes because the delay layer helps in delaying the delivery of the active agents from the dosage forms following the administration of the dosage form to a patient in need of drug therapy and the dosage form with the convex configuration as taught by Eckenhoff and Theeuwes successfully aid in delivering a beneficial agent. One skilled in the art would have been motivated to manipulate the viscosities of drug and the delay layer by the teachings of Jao et al as Jao et al. teaches how the manipulations of viscosities can affect the release rates of the drug.

Motivated by the teachings of various dosage forms with specific geometrical configurations, as discussed in the aforementioned references, a skilled artisan would have prepared a dosage form comprising (a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable; (b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semipermeable portion of the membrane;(c) a delay layer located adjacent the exit orifice; (d) a drug layer located within the compartment between the delay layer and the expandable layer; and (e) an interface boundary between the delay layer and the

drug layer, the interface boundary being convex in shape relative to the exit orifice with a reasonable expectation of success.

6. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/62496 ('496) in view of Jao et al. (US patent no. 5252338) and further in view of Eckenhoff et al. (US patent No. 4717566), Theeuwes (US Patent no. 4,111,202) and Physicians Desk Reference of record.

The references cited above do not specifically teach cyclobenzaprine. Physicians Desk Reference teaches that cyclobenzaprine HCl relieves skeletal muscle spasm. It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to make dosage form comprising cyclobenzaprine because of its therapeutic use. A skilled artisan would thus have been motivated to formulate a dosage form as claimed with a reasonable expectation of success.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit

1615

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500